93. The method of eliciting a protective immune response according to claim 81, wherein the group A polysaccharide is administered in a dosage amount of about 0.1 μg to about 10 μg per kilogram of body weight.

REMARKS

Support for the new claims is found throughout the specification. For example, claim 80 is supported by original claim 26 and at page 10, lines 23-29 and page 11, lines 20-28. Claim 81 is supported by original claim 34, and claims 82-84 by original claims 27-29, respectively. Claims 85-88 are supported by page 11, line 70 through page 12, line 4 and by page 13, line 14 through page 15, line 10. Claims 89-93 are supported by original claims 31-33, 35 and 30, respectively. No new matter is introduced by the Amendment. Entry of the Amendment is respectfully requested.

Response Specification Objection

The description for Figure 1 in the specification was objected to for not referring to Figure 1A and Figure 1B. Applicants have amended the description to comply with the Examiner's suggestion.

Response To Section 102 Rejection

Claims 61-63, 68 and 69 were rejected under 35 U.S.C. § 102(b) for being anticipated by Reimer et al. (1992) *Carbohyr. Res.* 232:131. The Examiner contends that applicants' polysaccharide conjugate of about 3 to about 30 repeat units is anticipated by Reimer's description of a polysaccharide conjugate having only one complete repeat unit. Applicants respectfully disagree with this rejection.

Based on the specification of the instant application, one skilled in the art would not interpret "about 3" to describe a range which would read on the polysaccharide reported by Reimer. Applicants' specification defines a preferred range for n as being from about 1 to about 50. A more preferred range for n is defined as being from about 3 to about 30. See page 11, lines 5-10. The preferred and more preferred ranges are not co-extensive. Thus, one skilled in the art would not interpret "about 3" to be 3 ± 2 or 3 ± 1.5 since such an interpretation would create a more preferred range that is co-extensive with a less preferred range. Further, Reimer does not teach a method of immunizing a mammal against infection by group A Streptococci. Therefore, Reimer fails to anticipate applicants' claims.

The Examiner states that the "[i]nstant claims are directed to a method of immunizing a mammal comprising administering an immunogenic amount of the recited polysaccharide of formula (I) covalently linked to a protein, wherein n in the formula encompasses a number of 'about 3.' The claimed method is not required to induce protection." Office Action mailed June 12, 2001 at page 4, second full paragraph, emphasis added. Applicants assert that Reimer neither teaches or suggests a polysaccharide conjugate of about 3 repeat units, nor teaches or suggests a method of eliciting a protective immune response in a mammal. However, noting the Examiner's suggestion to amend the claims to require inducement of protection, applicants have included reference to protection in the new claims as suggested by the Examiner. The amendment was made to avoid protracted prosecution to reestablish that applicants' polysaccharide conjugate of about 3 repeat units is not anticipated by Reimer. Applicants respectfully request consideration of the new claims and withdrawal of this rejection. Because Reimer neither teaches nor suggests a method that confers protection, claim 1 has been amended to recite that the polysaccharide component is of sufficient weight to produce a protective polysaccharide

protein conjugate or polysaccharide protein fragment conjugate. Consideration of the new claims and withdrawal of this rejection is respectfully requested.

Response To Section 103 Rejection

Claims 61-72 were rejected under 35 U.S.C. § 103(a) for being unpatentable over Reimer in view of Jennings et al. U.S. 4,356,170 and Barnes et al. WO 871/06590. Applicants respectfully disagree with this rejection.

In particular, the Examiner states that "the instant claims are drawn to a method of 'immunizing a mammal' as opposed to a method of 'eliciting a protective immune response in a mammal.'" Office Action mailed June 12, 2001 at page 5, first full paragraph. Applicants assert that the cited art does not provide motivation to modify Reimer to arrive at applicants' claimed invention. However, to avoid protracted prosecution to reestablish this fact, applicants have relied on the Examiners suggestion to recite a method of "eliciting a protective immune response in a mammal." Applicants believe that inclusion of this phrase in the present claims overcomes all rejections based on the combination of Reimer, Jennings and Barnes. Consideration of the new claims and withdrawal of this rejection is respectfully requested.

Claims 61-63, 68 and 69 were rejected under 35 U.S.C. § 103(a) for being unpatentable over Reimer. Applicants respectfully disagree with this rejection. For example, the Examiner bases the rejection, in part, on the contention that the structures on pages 135 and 136, which depict $[.....]_n$, suggest polysaccharide conjugates with two or more branch points. This contention is in error. Each of the structures within the brackets show the man-made linker —$O(CH_2)_8CONH$— as part of the structure within the brackets. If n referred to the number of repeating units as the Examiner contends, the resulting structure would not be a group A streptococcal polysaccharide. Rather, n refers to the

number of polysaccharide molecules (which consist of only a single complete repeat unit) that are attached to a single protein molecule. See page 132 under "Glycoconjugates and oligosaccharide haptens."

However, to avoid protracted prosecution to reestablish patentability of applicants' invention, applicants have relied on the Examiners suggestion to recite a method of "eliciting a protective immune response in a mammal." Applicants believe that inclusion of this phrase in the present claims overcomes all rejections based on Reimer. Consideration of the new claims and withdrawal of this rejection is respectfully requested.

Claims 61-72 were rejected under 35 U.S.C. § 103(a) for being unpatentable over Reimer in view of Jennings et al. U.S. 4,356,170 and Barnes et al. WO 871/06590. Applicants respectfully disagree with this rejection.

To avoid protracted prosecution to reestablish patentability of applicants' invention, applicants have relied on the Examiners suggestion to recite a method of "eliciting a protective immune response in a mammal." Applicants believe that inclusion of this phrase in the present claims overcomes all rejections based on the combination of Reimer, Jennings and Barnes. Consideration of the new claims and withdrawal of this rejection is respectfully requested.

Response to Double Patenting Rejection

Claims 61-72 were rejected under the judicially created doctrine of obviousness-type double patenting for being unpatentable over claims 26-33 of U.S. Patent No. 5,866,135. Applicants respectfully disagree with this ground of rejection.

However, Applicants agree to file a terminal disclaimer upon allowance of claims in this application. The filing of a terminal disclaimer to obviate a rejection based on nonstatutory double patenting is not an admission of the propriety of the rejection. *Quad*

Environmental Technologies Corp. v. Union Sanitary District, 946 F.2d 870 (Fed. Cir. 1991).

AUTHORIZATION

No additional fee is believed due for filing this paper. However, should any additional fee be required, the Commissioner is hereby authorized to charge any fee or credit any overpayment to Deposit Account No. 13-4500, Order No. 2016-4005US1.

In addition, the Commissioner is requested to grant a petition for any extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 13-4500, Order No. 2016-4005US1.

Respectfully submitted,

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Dated: October 15, 2001

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APPENDIX
Version With Markings To Show Changes Made

Fig. 1 schematically represents the structural design of group A carbohydrate (Fig. 1A) and the group A Variant carbohydrate (Fig. 1B). The depiction of the three dimensional structure of the group A carbohydrate clearly supports the observation that the serological specificity of the carbohydrate is directed towards the N-acetylglucosamine [N-acethylglucosamine] moiety of the carbohydrate.